device, a copy of all labeling for the device.

(2) For a device that is a restricted device, a copy of all labeling for the device, a representative sampling of advertisements for the device, and for good cause, a copy of all advertisements for a particular device. A request for all advertisements will, where feasible, be accompanied by an explanation of the basis for such request.

(3) For a device that is neither a restricted device, nor subject to section 514 of 515 of the act, the label and package insert for the device and a representative sampling of any other labeling for the device.

(4) For a particular device, a statement of the basis upon which the registrant has determined that the device is not subject to section 514 or 515 of the act.

(5) For a particular device, a statement of the basis upon which the registrant has determined the device is not a restricted device.

(6) For a particular device, a statement of the basis for determining that the product is a device rather than a drug.

(7) For a device that the owner or operator has manufactured for distribution under a label other than its own, the names of all distributors for whom it has been manufactured.

(f) Labeling, advertisements, and other information to be submitted upon request in accordance with paragraph (e) of this section may be submitted by postal mail or electronically by email, but will not be submitted using the FDA electronic device registration and listing system. Electronic submissions of such information must comply with part 11 of this chapter, except for the requirements in § 11.10 (a), (c) through (h), and (k), and the corresponding requirements in § 11.30 of this chapter. The information provided in electronic format must be in a form that we can process, review, and archive.

[43 FR 37999, Aug. 25, 1978, as amended at 51 FR 33033, Sept. 18, 1986; 63 FR 5253, Feb. 2, 1998. Redesignated and amended at 77 FR 45943, Aug. 2, 2012]

§ 807.28 Updating device listing information.

(a) Updating of device listing information is required if an additional establishment begins to engage in any of the activities described in § 807.3(d) with respect to a listed device, such as manufacturing, developing specifications, repackaging, relabeling, or otherwise processing the device. Updating of the listing is also required if an establishment begins performing another activity on or to the device, or ceases to perform an activity on or to the device that had previously been identified on the device listing.

(b) An owner or operator shall create a new device listing using the FDA electronic device registration and listing system:

(1) If introducing into commercial distribution an exempt device identified with a product code that is not currently listed by the owner or operator; or

(2) If introducing into commercial distribution a non-exempt device with an FDA premarket submission number that is not currently listed by the owner or operator.

(c) All device listings for foreign establishments must be submitted before the device may be imported or offered for import into the United States.

(d) An owner or operator who discontinues commercial distribution of a device shall discontinue the device listing using the FDA electronic device registration and listing system. A device listing is considered discontinued if:

(1) All devices under an exempt product code have been discontinued or

(2) All devices associated with an FDA premarket submission number have been discontinued.

(e) If commercial distribution of a discontinued device is resumed, the owner or operator must reactivate the previously-discontinued listing using the electronic device registration and listing system. Any changes to the listing information for the product that is the subject of the listing such as a new establishment, new activity, or new proprietary name must be made using the electronic device registration and listing system at the time the listing is reactivated.

(f) FDA will assign one listing number for all devices exempt from premarket notification requirements under a single product code. For products not exempt from premarket notification requirements, a single listing number will be assigned by FDA for each FDA premarket submission number.

[77 FR 45943, Aug. 2, 2012]

§ 807.34 Summary of requirements for owners or operators granted a waiver from submitting required information electronically.

(a) For initial registration and listing, owners or operators who have been granted a waiver from electronic filing using the procedures set forth in § 807.21(b) must send a letter containing all of the registration and listing information described in §§ 807.22, 807.25, (and § 807.26 when such information is requested by FDA), at the times described in § 807.22, to: The Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3521, Silver Spring, MD 20993–0002.

(b) As specified in § 807.22(b)(1) and (b)(3), all owners or operators shall update their establishment registration and device listings annually during the period beginning on October 1 and ending on December 31 of each fiscal year.

(c) Failure to submit any of the required information on time, as specified in § 807.22(a) and (b), will put the establishment in a ''failed to register'' or ''failed to list'' status as applicable.

The establishment will not be considered active and the establishment registration and device listing information may not appear on the FDA Web site until the required information is submitted to and processed by FDA.

[77 FR 45943, Aug. 2, 2012]

§ 807.35 Notification of registrant.

(a) The Food and Drug Administration will assign each device establishment a registration number after verifying the initial establishment registration information that has been submitted. The owner or operator of the establishment will also be assigned an identifying number. Both numbers will be sent to the official correspondent by email, or by postal mail if the owner or operator has been granted a waiver from the requirement to file registration and listing information electronically.

(b) Owners or operators of device establishments who also manufacture or process biological products (including devices licensed under section 351 of the Public Health Service Act) or drug products at the same establishment must also register and list those products under part 607 or part 207 of this chapter, as appropriate. Registration and listing for human blood and blood products, devices licensed under section 351 of the Public Health Service Act, and licensed biological products used in the manufacture of a device licensed under section 351 of the Public Health Service Act, are subject to part 607 of this chapter; registration and listing for all other drug products (including other biological products that are also regulated as drug products) are subject to part 207 of this chapter.

(c) Although establishment registration and device listing are required to engage in the device activities described in § 807.20, validation of registration and the assignment of a device listing number in itself does not establish that the holder of the registration is legally qualified to deal in such devices and does not represent a determination by the Food and Drug Administration as to the status of any device.

[69 FR 11312, Mar. 10, 2004, as amended at 77 FR 45943, Aug. 2, 2012]

§ 807.37 Public availability of establishment registration and device listing information.

(a) Establishment registration and device listing information is available for public inspection in accordance with section 510(f) of the Federal Food, Drug, and Cosmetic Act and will be posted on the FDA Web site, with the exception of the information identified in paragraph (b) of this section. Requests for information by persons who do not have access to the Internet should be directed to the Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave.,